

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

May 25, 2017

The Honorable Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

We write to follow up on the Committee's oversight of management concerns at the NIH Clinical Center, and to help ensure that NIH succeeds in the corrective actions it has taken.

Almost two years ago, in response to concerns raised by a whistleblower, the FDA conducted an inspection of the NIH Clinical Center Pharmacy, finding a series of deficiencies in the Pharmaceutical Development Section (PDS) physical facility. In addition, two vials of albumin, used for administration of the drug interleukin in experimental studies, were found to have fungal contamination. The contamination potentially affected hundreds of participants in 46 studies, and six patients were administered drugs from vials made from the contaminated batch. On June 4, 2015, the NIH Clinical Center suspended operations of its Pharmaceutical Development Section after the discovery of serious manufacturing problems and lack of compliance with standard operating procedures.

The severity of the deficiencies, the disruption of ongoing studies, and the resulting suspension of PDS operations raised serious questions about the management of the NIH PDS for the last several years. In light of these concerns, the Committee launched an investigation into this matter on July 30, 2015. As part of this investigation, the bipartisan staff of the Committee came to the NIH campus on June 30, 2016, for an *in camera* review of documents related to questions 1, 2, and 4 in the Committee's May 26, 2016 request letter to the NIH.

We appreciate your statements to Committee leaders, in person and in writing, that you take this matter very seriously and have personally overseen a number of corrective actions. In response to the deficiencies uncovered by the FDA, you commissioned a report from a subcommittee of the Advisory Committee to the Director called the "Red Team" to determine

the underlying causes of the PDS problems and to recommend a way forward designed to prevent similar problems from happening in the future. The NIH released the Red Team report on April 21, 2016. It concluded that deficiencies in practices in the PDS facilities—such as failure to comply with current good manufacturing standards, a tendency to emphasize research ahead of safety concerns, and inadequate reporting systems—were to some extent systemic and not limited to the PDS. Among the corrective actions taken were organizational changes to oversee and enforce new safety and compliance standards including a new Research Support and Compliance office in the Office of the Intramural Research, a new Clinical Practice Committee to set standards for all clinical practice at the NIH; and an external hospital board.

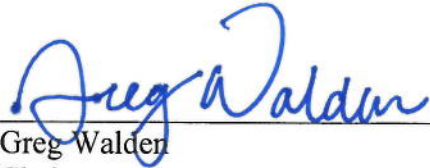
Given that a year has passed since NIH announced a series of corrective actions and new oversight mechanisms, we are following up to understand what further insights and information NIH has obtained from these additional reviews, and any further corrective actions that the NIH is taking. Further, the Committee's investigation, including the *in camera* review of documents, has found additional information and issues related to the management of the NIH PDS and possibly the NIH Clinical Center not included in the NIH internal and external reviews. We want to ensure that NIH's corrective actions are effectively addressing concerns related to the NIH Clinical Center. The documents provided in the *in camera* review are critical for the Committee to have for internal use to facilitate an accurate and complete understanding of the context of these issues and to determine whether these issues are fully addressed by NIH's corrective actions.

Pursuant to Rules X and XI of the U.S. House of Representatives, please provide the following by June 8, 2017:

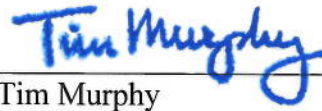
1. All audits, reports, internal reviews, or analysis related to safety and compliance practices, concerns, performance, recommendations, or corrective actions at the NIH Clinical Center, generated for or by any NIH office, NIH contractor, or NIH advisory committee/subcommittee since April 21, 2016, including but not limited to the Research Support and Compliance office in the NIH Office of Intramural Research, the Clinical Practice Committee, and the NIH Clinical Center's hospital board.
2. All documents related to questions 1, 2, and 4 in the Committee's May 26, 2016 request letter to the NIH that were part of the June 30, 2016 bipartisan committee staff *in camera* review at the NIH campus.

Thank you for your assistance with this request. An attachment to this letter provides additional information about how to respond to the committee's request. If you have any questions regarding this request, please contact Alan Slobodin, Emily Felder, or Brittany Havens of the majority committee staff at (202) 225-2927.

Sincerely,

A handwritten signature in blue ink that reads "Greg Walden". The signature is written in a cursive style with a large, looping "G".

Greg Walden
Chairman
Committee on Energy and Commerce

A handwritten signature in blue ink that reads "Tim Murphy". The signature is written in a cursive style with a large, looping "T".

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

cc: The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Attachment